UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/216,604	12/17/98	GUO	Y

022249
LYON & LYON LLP
SUITE 4700
633 WEST FIFTH STREET
LOS ANGELES CA 90071-2066

HM12/0329

EXAMINER	
DIBRINO, M	
ART UNIT	PAPER NUMBER
1644	5

DATE MAILED: 03/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/216,604	Guo, Y.
Examiner	**Group Art Unit**
Marlann DiBrino	1644

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-22* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-22* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hassle, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-4 and 6, drawn to a method of preparing a pharmaceutical composition for stimulating T cells comprising treating target diseased cell to increase levels of one or more primary and costimulatory molecules and said composition comprising an autologoous diseased target cell and a bridge molecule, classified in Class 424, subclasses 136.1 and 93.7, respectively.

II. Claims 5 and 12-16, drawn to a method of preparing a pharmaceutical composition for stimulating T cells comprising expressing one or more antigens from diseased cells in antigen presenting cells and said composition comprising a cytokine and a bridge molecule, classified in Class 435, subclass 455 and Class 424, subclass 277.1.

III. Claims 7-9, drawn to a method of in vivo treatment of a patient having a tumor comprising providing a cytokine and a bridge molecule and a composition/kit comprising said cytokine and said bridge molecule, classified in Class 424, subclass 85.1.

IV. Claims 10 and 11, drawn to a composition and a kit comprising a cytokine and a bridge molecule, classified in Class 424, subclass 85.2.

V. Claim 17, drawn to a method of in vitro generation of CTL comprising bringing into contact with T cells, cells which express one or more primary and costimulatory T cell activation molecules at a higher level than that in diseased cells in a patient mammal attached to a bridge molecule, classified in Class 435, subclass 325.

VI. Claim 18, drawn to a method of in vitro generation of CTL comprising bringing into contact with T cells, APC which present antigen(s) of the diseased cells in the context of MHC class I or II, said cells attached to a bridge molecule, Classified in Class 435, subclass 325.

VII. Claims 19-22, drawn to a method of in vivo treatment of a patient having a tumor, comprising providing first and second bridge molecules, classified in Class 424, subclass 138.1.

3. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as in vivo for the production CTL, or for targeting the product to tumor cells.

4. Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as in vivo for the production CTL, or for targeting the product to tumor cells.

5. Inventions IV and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as for the in vitro production of CTL against a tumor antigen.

6. Inventions I, II, III, V, VI and VII are different methods.

These inventions require different ingredients, process steps and endpoints. For example, Inventions I and II are methods of making different pharmaceutical compositions, comprising different process steps, i.e., treating a target diseased cell to increase levels of one or more primary and costimulatory molecules vs expressing one or more antigens from diseased cells in antigen presenting cells (APC), respectively. The methods of Inventions III and VII are methods of in vivo treatment of tumors, comprising using different process steps, i.e., providing a cytokine and bridge molecule vs providing a first and second bridge molecule, respectively. The meethods of Inventions V and VI are methods of in vitro generation of CTL, comprising different process steps, i.e., bringing T cells into contact with: cells which express one or more primary and costimulatory T cell activation molecule vs APC which present antigen(s)/MHC of the diseased cells, respectively.

Therefore they are patentably distinct.

7. Inventions I, II and IV are different products.

Said inventions comprise cytokines, bridging molecules (which can be bispecific antibodies), cells induced to express high levels of T cell activation and costimulatory molecules and APCS. Cytokines and antibodies are different proteins which have different physicochemical properties and modes of function. Cytokines and antibodies are different from cells. Cells induced to express high levels of T cell activation and costimulatory molecules are different from APCS which are not.

Therefore they are patentably distinct.

8. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-VII is not required for any other group from Groups I-VII and Groups I-VII have acquired a separate status in the art as shown by their different classification and divergent subject

matter, restriction for examination purposes as indicated is proper.

9. Irrespective of whichever Invention Applicant may elect, Applicant is further required under 35 U.S.C. 121 (1) to elect a single disclosed species:

a. If one of Inventions I, II, III, V, VI or VII is elected, Applicant is required to elect a **specific method employing a specific species of bridge molecule such as for example, a bispecific antibody such as CD28:gp55;**

b. If Invention II or VI is elected, Applicant is also further required to elect **a specific method employing a specific species of antigen from diseased cells and a specific species of bridge molecule such as for example, a bispecific antibody such as CD28:gp55;**

c. If one of Inventions I, II or IV is elected, Applicant is required to elect **a composition comprising a specific species of bridge molecule such as for example, a bispecific antibody such as CD28:gp55.**

These species are patentably distinct because they are different proteins with different physicochemical characteristics.

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist

whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
March 27, 1999

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800 1640